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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,180	02/11/2004	Craig A. Rosen	PF574	1800

22195 7590 10/03/2005

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EXAMINER	
CARLSON, KAREN C	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/775,180	ROSEN ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

SD

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1-161, claim(s) 1-13, drawn to albumen fusion proteins NO: 1 to NO: 161, respectively, from Table 2, Class 530/350.

162-322, claim(s) 14, drawn to method of treating disease via administration of albumen fusion proteins NO: 1 to NO: 161, respectively, from Table 2, Class 514/2.

323-483, claim(s) 15, drawn to method of treating metabolic disorders via administration of albumen fusion proteins NO: 1 to NO: 161, respectively, from Table 2, Class 514/2.

484-644, claim(s) 16-25 and 27, drawn to method of treating diabetes via administration of albumen fusion proteins NO: 1 to NO: 161, respectively, from Table 2, Class 514/2.

645-805, claim(s) 26 and 28, drawn to method of treating obesity via administration of albumen fusion proteins NO: 1 to NO: 161, respectively, from Table 2, Class 514/2.

806-966, claim(s) 29, drawn to method of extending the shelf life of albumen fusion proteins NO: 1 to NO: 161, respectively, from Table 2, Class 514/2.

967-1127, claim(s) 30-32, drawn to nucleic acid encoding albumen fusion proteins NO: 1 to NO: 161, respectively, from Table 2, Class 536/23.1.

The inventions are distinct, each from the other because of the following reasons:

Regarding Inventions 1-161, the albumen fusion proteins NO: 1 differs in structure and function from albumen fusion proteins NO: 2-NO: 161 because the attached therapeutic protein is different for each fusion protein as set forth in Table 2 beginning on page 43 of the specification. Therefore, Inventions 1-161 are patentably distinct one from the other.

The nucleic acids of Inventions 967-1127 are related to the proteins of Invention I-161, respectively, by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in the Claims of Invention I. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

Inventions 1-161 and Inventions 162-322, respectively, Inventions 323-483, respectively, Inventions 484-644, respectively, Inventions 645-805, respectively, and Inventions 806-966, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP □ 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in any one of Inventions 162-322, respectively, Inventions 323-483, respectively, Inventions 484-644, respectively, Inventions 645-805, respectively, and Inventions 806-966, respectively.

The DNA of Inventions 967-1127 are not used in anyone of the methods of Inventions 162-966. Therefore, Inventions 967-1127 are patentably distinct from Inventions 162-966.

Inventions 162-322, respectively, Inventions 323-483, respectively, Inventions 484-644, respectively, Inventions 645-805, respectively, and Inventions 806-966, respectively, are methods that use different products and/or different method steps. Therefore, Inventions 162-322, respectively, Inventions 323-483, respectively, Inventions 484-644, respectively, Inventions 645-805, respectively, and Inventions 806-966, respectively are patentably distinct one from the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

F.P.: Ochiai/Brouwer Rejoinder form paragraph

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

> In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**
>
> Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen Cochrane Carlson PhD

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KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER